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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,151	05/18/2006	George C. Prendergast	3882-P03161US2	4302

110 7590 10/15/2008  
DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER
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STONE, CHRISTOPHER R

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,151	<b>Applicant(s)</b> PRENDERGAST ET AL.	
	<b>Examiner</b> CHRISTOPHER R. STONE	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-37, 40 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 41-47, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/13/2008, 03/12/2008</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed July 7, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 39 and 41-47, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer, does not reasonably provide enablement for the treatment other cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 38, 39 and 41-47, 53 and 54 are drawn to a method of treating cancer comprising administering an IDO inhibitor and a chemotherapeutic compound. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination. The prior art indicates that cancer is a group of maladies not treatable with one medicament or therapeutic regime. No single chemotherapeutic drug is useful for the treatment of every

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case of cancer. In fact, some types of cancer do not respond well to any known chemotherapeutic drugs (see Oxford Textbook of Oncology, p. 451, Column 2, last paragraph). These negative results indicate the unpredictability of the art. Furthermore, the applicant has provided no working examples demonstrating the efficacy of this treatment on cancers other than breast cancer. For these reasons, it would take undue experimentation by one of ordinary skill in the art to use this method to treat cancers, other than breast cancer, with a reasonable expectation of success.

Applicant argues that the art filed, July 7, 2008, demonstrates the effectiveness of the instantly claimed compounds against several different cancer types and that in light of this broad range of efficacy the instantly claimed method is enabled for the treatment of cancer. This is not found persuasive. Figure 1A of Hou et al does not demonstrate the efficacy of the method of treatment currently under examination, i.e. a method of treating cancer comprising administering Methyl-TH-DL-Trp or 1-methyl-DL-tryptophan (1MT), and cisplatin, on other cancers. Hou et al is drawn to the treatment of melanoma xenografts using cyclophosphamide and 1MT. Figure 2 is drawn to the treatment of breast cancer comprising administering 1MT and cyclophosphamide or paclitaxel. Additionally, 1MT has no effect when administered alone (see figure 1A, 2), lending no support to the efficacy of the instantly claimed treatment against other tumor types. Kumar et al does not demonstrate the efficacy of the method of treatment currently under examination on other cancers. Kumar et al is drawn to a method of treating breast tumors comprising administering vitamin K3 and paclitaxel. Muller et al does not demonstrate the efficacy of the method of treatment currently under

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examination on other cancers. Muller et al is drawn to the treatment of breast cancer comprising administering methyl-TH-DL-trp and paclitaxel. methyl-TH-DL-trp has no effect when administered alone (see figure 6), lending no support to the efficacy of the instantly examined treatment against other tumor types.

The declaration under 37 CFR 1.132 filed, July 7, 2008, is insufficient to overcome the rejection of claim 38, 39 and 41-47, 53 and 54. The declaration does not demonstrate the efficacy of the method of treatment currently under examination, i.e. a method of treating cancer comprising administering Methyl-TH-DL-Trp or 1-methyl-DL-tryptophan (1MT), and cisplatin, on other cancers. The declaration is drawn to treating lung and colon cancer comprising administering 1MT and cyclophosphamide. Additionally, 1MT has no effect when administered alone (see Exhibits A and B), lending no support to the efficacy of the instantly claimed treatment against other tumor types.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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02October2008

CRS

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614